

REMARKS

Claims 16, 18–27 and 33–34 are pending in the present Application. Claims 26–27 are amended and claims 33–34 are new. These amendments do not introduce new matter. Support may be found in the specification, for example, at page 6, lines 1–5 and page 9, lines 1–2, etc. Applicant respectfully requests reconsideration of the Application in light of these amendments and the following remarks.

Obviousness

The Office Action rejects the pending claims as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,355,772 (“Gruber”) in view of U.S. Patent No. 3,047,524 (“Bowman”) as evidenced by U.S. Patent No. 4,273,920 (“Nevin”).

As currently amended, claim 16 recites, among other limitations, a catalytic system comprising a strongly acidic ion-exchange resin polymeric catalyst and a (co)oligomerization additive of the general formula (2) for the (co)oligomerization of lactide and/or glycolide by ring opening. The claim also requires that the quantity of monomer relative to the quantity of (co)oligomerization additive ranges from 2 to 30 molar equivalents. Gruber discloses a melt-stabilized lactide polymer nonwoven fabric, but does not teach or suggest combining:

- (1) a strongly acidic ion-exchange resin polymeric catalyst, with***
- (2) the claimed (co)oligomerization additive.***

The claimed combination of components (1) and (2) results in conversions of 95% of lactide and/or glycolide monomers without the use of a metal-organic catalyst, thereby avoiding contamination yet retaining sufficient conversion to be commercially feasible.

Gruber is directed to melt-stabilized lactide polymer nonwoven fabrics. In general, these fabrics are made from poly(lactide) polymer chains that have a “number average molecular weight of from about 10,000 to 300,000” polymerized with metal-containing catalytic systems. Gruber, col. 5, ll. 21–23; Examples 11–13. The only catalytic systems disclosed by Gruber as achieving an adequate molecular weight to serve as a nonwoven fabric are metal catalyst systems. But Gruber does include one example, Example 8, that uses Amberlyst 36 resin beads as a catalyst. The Amberlyst 36 polymerization produced a polymer having number average molecular weight of 1,112, which is well below Gruber’s desired number average molecular weight from about 10,000 to 300,000. Nevertheless, the Office Action focuses on Gruber’s unsuitable Amberlyst 36 example as a starting point for obviousness because it is the only

catalytic system disclosed by Gruber that includes a “strongly acidic ion-exchange resin polymeric catalyst.”

Gruber discloses a molecular weight control agent that is expressly “added in sufficient quantity to control the number average molecular weight of the poly(lactide) to ***between about 10,000 and about 300,000.***” Gruber, col. 15, ll. 12–15 (emphasis added). On its face, the molecular weight control agent teaching of Gruber cannot apply to the ineffective Amberlyst 36 resin system since the molecular weight control agent is disclosed as effective for controlling Mn between about 10,000 and about 300,000, yet the Amberlyst 36 resin system produced a polymer with an unsuitable Mn of 1,112, which is outside the effective range for the molecular weight control agent. In fact, Gruber only applies the molecular weight control agent to its metal catalyst systems that produce polymer within the range of between 10,000 and 300,000 Mn. For example, at col. 25, ll. 49-53, Gruber discloses the use of lactic acid (*not lactide*) as “a molecular weight control agent to target a number average molecular weight of 50,000” in a tin(II) bis (2-ethyl hexanoate) system. As the molecular weight control agent is used to target molecular weight between 10,000 and 300,000, it is unclear how the agent would be used in a catalytic system that is incapable of producing polymers having a Mn of within this range such as the Amberlyst 36 example of Gruber.

The Office Action fails to set forth a *prima facie* case of obviousness. The present claims distinguish over the Amberlyst 36 polymerization in Example 8 of Gruber by requiring the claimed “(co)oligomerization additive,” which can be water or an alcohol. The claims further distinguish over trace quantities of water or alcohol in such a system by also requiring that the “quantity of monomer relative to the quantity of (co)oligomerization additive ranges from 2 to 30 molar equivalents.” The Amberlyst 36 polymerization of Gruber fails to include either water or alcohol in the claimed ratio to the monomer. There is no discussion of water in the polymerization and although dry methanol is used to clean the resin, it is dried for several hours under vacuum. Under these aggressive drying conditions, only trace quantities of methanol, if any, would have been present during the polymerization. Furthermore, the % conversion reported by Gruber of 73.5% is lower than that achieved by the present invention, which was greater than 95%. Accordingly, it is clear that the ineffective Amberlyst 36 example of Gruber does not meet the “(co)oligomerization additive” limitation as claimed.

The Office Action proposes that it would have been obvious to modify the ineffective Amberlyst 36 example of Gruber by including the molecular weight control agent as a (co)oligomerization additive. First, the Office Action fails to set forth any reason a person having ordinary skill in the art would have started with the ineffective Amberlyst 36 example of Gruber, given that Gruber was directed to nonwoven fabrics with Mn ranging from 10,000 to 300,000, yet the Amberlyst 36 example resulted in a Mn of 1,112 which is unsuitable for a nonwoven fabric. Second, the Office Action fails to set forth any reason a person having ordinary skill in the art would have combined the molecular weight control agent with the ineffective Amberlyst 36 catalytic system. As noted above, the control agent sought to control Mn between 10,000 and 300,000, yet the Amberlyst 36 example falls well outside this range with an unsuitable Mn of 1112.

Finally, the present application teaches that the (co)oligomerization additive “is indispensable because in the absence of such a compound . . . the (co)oligomerization reactions are much slower, lead to much smaller yields, and are not reproducible, and therefore cannot be exploited industrially.” Specification, page 4. The examples 1–8 of this application utilize a catalytic system similar to that of the Amberlyst 36 resin of Gruber, but differ from Gruber by the addition of the claimed (co)oligomerization additive. In every example of this specification, the percent conversion of the monomer was greater than 95%. In contrast, the maximum conversion achieved by Gruber is for a “strongly acidic ion-exchange resin polymeric catalyst” was 73.5%. **As such, the present invention resulted in at least a 20% increase in conversion of the monomer (to greater than 95%) relative to prior art that did not include the claimed (co)oligomerization additive.** Based on these results, it is clear that (1) Gruber did not use a (co)oligomerization additive in its Amberlyst 36 polymerization as a conversion of only 73.5% was attained, and (2) the prior art as represented by Gruber did not recognize the unexpectedly beneficial effect of using a (co)oligomerization additive with the claimed catalytic system. For at least these reasons, Gruber alone fails to render the claimed invention obvious.

Neither Bowman nor Nevin cure the deficiencies of Gruber as both references relate to lactic acid and/or glycolic acid condensation or addition systems and disclosed absolutely nothing that can be applied to a lactide and/or glycolide ring opening catalytic system. The Office Action is incorrect that the “polymerization of glycolic acid . . . is analogous to polymerization of lactic acid disclosed by Gruber.” Initially, lactide (a dimer ring) and lactic acid

not the same. Gruber discloses conversion of lactide to PLA using a *ring-opening polymerization*. Bowman and Nevin are both directed to conversion of lactic acid (and/or glycolic acid) to PLA (and/or PLGA or PGA) using an *addition or condensation polymerization*. These are different catalytic systems. For example, in the metal-catalyst systems of Gruber, lactide is the monomer and lactic acid serves as the molecular weight control agent. In contrast, lactic acid is the monomer in the disclosure of Bowman and Nevin, while Nevin clearly states that any glycolide or lactide formed as byproducts are removed by distillation. Nevin, col. 3, ll. 37–39. Accordingly, a person of ordinary skill in the art would not extrapolate the use of one component in an addition or condensation polymerization to the use of a similar component to a ring-opening polymerization. Accordingly, the Office Action is incorrect in relying on Bowman and/or Nevin to modify the lactide polymerization of Gruber. As there was no reason a person having ordinary skill would have modified Gruber in light of Bowman and/or Nevin, the rejection of the present claims as being obvious over these references is improper and must be withdrawn.

Claims 18–27 are dependent on claim 16, which, as amended, has been shown to be patentable over Gruber and Gruber in view of Bowman. Applicant respectfully submits that claims 18–27, by virtue of their dependency from claim 16, are also patentable for the same reasons claim 16 is patentable. Accordingly, Applicant requests withdrawal of the rejection of claims 18–27 as being unpatentable under 35 U.S.C. § 103(a) over Gruber in view of Bowman.

New claim 33 depends from claim 16 and further specifies that the conversion of the monomer is greater than 95%. Gruber discloses a strongly acidic ion-exchange resin polymeric catalyst that does not include a (co)oligomerization additive, and therefore only achieves a conversion of 73.5%. For the reasons given above, Bowman and Nevin fail to cure the deficiencies of Gruber. As such, new claim 33 is allowable for this additional reason independent of the reasons given for claim 16 above.

New claim 34 depends from claim 16 and further specifies that the (co)oligomerization results in a degree of polymerization is less than 30. As noted above, Gruber discloses a molecular weight control agent that is expressly “added in sufficient quantity to control the number average molecular weight of the poly(lactide) to *between about 10,000 and about 300,000*.” Gruber, col. 15, ll. 12–15 (emphasis added). Gruber fails to suggest the use of a molecular weight control agent in a system having a degree of polymerization less than 30 as

claimed. Accordingly, new claim 34 is allowable for this additional reason independent of the reasons given for claim 16 above.

CONCLUSION

For at least the reasons set forth above, Applicant respectfully submits that the pending claims are in condition for allowance. Should the Examiner believe anything further is needed to place the application in condition for allowance, the Examiner is invited to contact Jeff B. Vockrodt at (202) 419-2021.

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